K103033

510(k) Summary

JAN 10 2011

Submitter:	Zimmer Trabecular Metal Technology, Inc. 10 Pomeroy Road Parsippany, New Jersey 07054
Author:	Kathleen M. Rutherford Associate Director, Regulatory Affairs
Contact Person:	Kathleen M. Rutherford Associate Director, Regulatory Affairs Telephone: (973) 576-0139 Fax: (973) 884-8792
Date:	October 12, 2010
Trade Name:	Trabecular Metal™ Fusion Device
Common Name:	Intervertebral Body Fusion Device
Classification Name and Reference:	Orthosis, Spinal Intervertebral Fusion 21 CFR § 888.3080, ODP

DEVICE DESCRIPTION

The Trabecular Metal™ Fusion Device is an interbody fusion device comprised wholly of Trabecular Metal. The Trabecular Metal™ Fusion Device is implanted in the cervical intervertebral disc space and is intended to facilitate vertebral fusion by stabilizing adjacent vertebrae, maintaining disc height, and preventing the collapsing of one vertebrae onto another.

The Trabecular Metal™ Fusion Device is offered in three cross sectional sizes and is available in various height options to accommodate variations in patient anatomy. The height is measured at the posterior aspect of the device. The device is trapezoidal in shape and is offered in lordotic and non-lordotic configurations, i.e., with 7 degree and 0 degree profiles. The superior and inferior surfaces of the device have a pattern of ripples and a central hole in the device extending in the superior-inferior direction for placement of bone graft. Additionally, certain parts of the proposed system contain a central slot on the anterior surface to allow interface with a central inserter.

INDICATIONS FOR USE

The Trabecular Metal™ Fusion Device is a cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with/ without radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Trabecular Metal Fusion Device is intended for use with supplemental fixation systems and with autogenous bone graft. The Trabecular Metal Fusion Device is implanted via an anterior approach.

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DEVICE TECHNOLOGICAL CHARACTERISTICS AND COMPARISON TO PREDICATE DEVICE(S)

The Trabecular Metal™ Fusion Device was shown to be substantially equivalent to legally marketed predicate devices. The predicate devices include Crystal by Spinal Elements (K073351), BAK/C Interbody Device by Zimmer (P980048), Affinity Anterior Cervical Cage by Medtronic Sofamor Danek (P000028), and Trabecular Metal Vertebral Body Replacement System by Zimmer (K070754).

The Trabecular Metal Fusion Device has the identical material as previously cleared predicate devices. The intended use and indications for use of the subject device are similar to those of its predicate devices. The sizes, design features and overall geometry of the device in the current submission are similar to the cleared predicate devices.

There are no significant differences between the Trabecular Metal Fusion Device and the predicate devices currently being marketed that would adversely affect the use of the product. Any differences in technological characteristics do not raise new issues of safety or efficacy. Animal testing demonstrated substantially equivalent performance of the device as compared to the predicate devices.

The subject system is similar to its predicate devices with respect to intended use/indications for use, material, technological characteristics and basic principles of operation.

PERFORMANCE DATA

Mechanical testing was performed on the Trabecular Metal Fusion Device which included Axial Compression – Static and Dynamic and Torsion – Static and Dynamic per ASTM F2077, Expulsion as recommended by the FDA *Class II Special Controls Guidance Document: Intervertebral Fusion Device*, and Subsidence per ASTM F2267. The results of testing and analyses conducted demonstrate that the proposed system adequately meets the predetermined requirements established for its mechanical performance.

An animal study was performed which compared the host bone response of the Trabecular Metal Fusion Device to that of the predicate device, Crystal by Spinal Elements which is made from polyetheretherketone (PEEK), in anterior cervical discectomy and interbody fusion procedures. Histological results confirmed definitive bone ingrowth and showed that The Trabecular Metal cervical interbody fusion implant supports bone growth into and around the implant margins.

CONCLUSION

The Trabecular Metal™ Fusion Device is substantially equivalent to its predicate devices with respect to intended use/indications for use, technological characteristics and basic principles of operation. As demonstrated by supporting performance data and the animal study data, these technological differences do not present any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Zimmer Trabecular Metal Technology, Inc.
% Ms. Kathleen M. Rutherford
Associate Director, Regulatory Affairs
10 Pomeroy Road
Parsippany, New Jersey 07054

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Re: K103033
Trade/Device Name: Trabecular Metal™ Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: October 12, 2010
Received: October 13, 2010

Dear Ms. Rutherford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103033

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Device Name: Trabecular Metal™ Fusion Device

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Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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